

REMARKS

Claims 1-8, 10, 12-17, 20-33, 35-40, 42, and 44-47, 50-64, 66-74 are pending upon entry of this Amendment C And Response to Office Action. Claims 1, 32, 62 and 70 have been amended herein to more particularly claim certain embodiments of the invention. Specifically, claims 1, 32, 62 and 70 have been amended to require the moisturizing and lubricating composition to comprise from about 0.05% (by weight) to about 5% (by weight) of an antioxidant, wherein the antioxidant is selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof. Support for these amendments can be found in originally filed claims 18, 19, 48, 49, and 65, as well as in the instant specification at paragraph [0076]. Claims 18, 19, 48, 49, and 65 have been cancelled. No new matter has been added by these amendments.

1. Rejections under 35 U.S.C. §103(a) over Krzysik, et al.

Reconsideration is requested of the rejection of claims 1-8, 10, 12-22, 25-30, 32, 33, 35-40, 42, 44-55, 58-60, 62-68, and 70-74 under 35 U.S.C. §103(a) as being unpatentable over Krzysik, et al. (WO 00/64409).

Claim 1, as amended herein, is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubricating composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by

weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 0.05% (by weight) to about 5% (by weight) of an antioxidant, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. The immobilizing agent is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles. The moisturizing and lubricating composition is at least about 40% soluble/dispersible in deionized water at a temperature of about 80°C. The antioxidant is selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, liponic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof.

Krzyśik, et al. disclose skin barrier enhancing absorbent tissues comprising a lipid-enriched melted hydrophilic composition. The composition comprises a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty alcohol (C_{14} - C_{30} or greater), a humectant, an oil-in-water emulsifying surfactant having an HLB range greater than 7, a sterol, and a

natural fat or oil. Specifically, in one exemplary embodiment, the composition comprises from about 10 to about 95 weight percent hydrophilic solvent, from about 5 to about 95 weight percent high molecular weight polyethylene glycol (preferably having a molecular weight of 720 or greater), from about 1 to about 30 weight percent of humectant, from about 1 to about 20 weight percent emulsifying surfactant having an HLB range greater than 7, from about 0.1 to about 10 weight percent of sterol or sterol derivative, and from about 0.1 to about 30 weight percent of natural fats or oils. Additional ingredients, such as antioxidants, may be added to the composition. After the composition is applied to a tissue, the composition is resolidified to form a distribution, preferably a uniform distribution, of solid deposits on the surface of the tissue.

Significantly, Krzysik, et al. fail to teach or suggest from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. § 2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103.

"[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."¹ The Court in KSR International further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art reference that would have led one of ordinary skill to modify the prior art reference to arrive at the claimed invention. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited reference fails to show each and every limitation of Applicants' invention and there is no

¹ *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

apparent reason for one skilled in the art to modify the reference to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Applicants respectfully submit that Krzysik, et al. fail to disclose a composition comprising from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthrocyanidins, and mixtures thereof. At best, Krzysik, et al. generally disclose that an antioxidant may be included in their composition to protect the integrity of the composition and to protect oxidation of the natural ingredients or other formulation components. Nowhere, however, do Krzysik, et al. disclose a suitable amount of the antioxidant that may be included in their composition, much less the specific antioxidants required by Applicants' amended claim 1. As such, Krzysik, et al. fail to teach each and every element of Applicants' amended claim 1.

Further, Applicants submit that there is no clearly articulated reason to modify Krzysik, et al. to arrive at the composition of Applicants' amended claim 1. Specifically, as Krzysik, et al. only generally disclose the inclusion of an antioxidant in a list of twenty-four optional ingredients, and nowhere disclose a suitable amount, why would one skilled in the art be motivated to include the optional antioxidant of Krzysik, et al. in Applicants' claimed amounts? Moreover, even if one

skilled in the art would and/or could be motivated to include an antioxidant in Krzysik, et al.'s composition in Applicants' claimed amounts (which Applicants assert is not the case), why would one be motivated to specifically choose an antioxidant as required by Applicants' amended claim 1 when Krzysik, et al. nowhere mention any specific antioxidants? One skilled in the art simply would not and could not be so motivated. As such, Applicants submit that claim 1, as amended, is patentable over the cited reference.

Claims 2-8, 10, 12-17, 20-22, 25-30, and 72 depend from claim 1 and are therefore patentable over the cited reference for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

Independent claim 32 is similar to claim 1 and further requires the moisturizing and lubricating composition to comprise a dispersing agent. As such, claim 32 is patentable over the cited reference for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires.

Claims 33, 35-40, 42, 44-47, 50-55, 58-60, and 73 depend directly or indirectly from claim 32 and are therefore patentable over the cited reference for the same reasons as set forth above for claim 32 as well as for the additional elements they require.

Claim 62 is similar to claim 1 and further requires the immobilizing agent to be a high molecular weight polyethylene glycol selected from the group consisting of PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. As such, claim 62 is patentable over

the cited reference for the same reasons as claim 1, as well as for the additional limitations it requires.

Claims 63, 64, 66, 68, and 74, which depend from claim 62, are patentable over the cited reference for the same reasons as claim 62, as well as for the additional limitations they require.

Claim 70 is similar to claim 1 and further requires the humectant to be selected from the group consisting of N-Acetyl ethanolamine, urocanic acid, aloe vera gel, arginine PCA, chitosan PCA, copper PCA, corn glycerides, dimethyl imidazolidinone, fructose, glucamine, glucose, glucose glutamate, glucuronic acid, glutamic acid, glycereth-7, glycereth-12, glycereth-20, glycereth-26, honey, hydrogenated honey, hydrogenated starch hydrolysates, hydrolyzed corn starch, lactamide MEA, lactic acid, lactose lysine PCA, mannitol, methyl gluceth-10, methyl gluceth-20, PCA, PEG-2 lactamide, PEG-10 propylene glycol, polyamino sugar condensate, potassium PCA, propylene glycol citrate, polyamino acid, polysaccharide, saccharide hydrolysate, saccharide isomerate, sodium aspartate, sodium lactate, sodium PCA, sorbitol, TEA-lactate, TEA-PCA, Urea, Xylitol, and mixtures thereof. Claim 70 is thus patentable over the cited reference for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires.

Claim 71, which depends from claim 70, is patentable over the cited reference for the same reasons as claim 70, as well as for the additional limitations it requires.

2. Rejections under 35 U.S.C. §103(a) over Krzysik, et al. in view of Bowser, et al.

Reconsideration is requested of the rejection of claims 1, 23, 24, 32, 56, 57, 62, and 67 under 35 U.S.C. §103(a) as being unpatentable over Krzysik, et al. (WO 00/64409) in view of Bowser, et al. (US 5,342,976).

Claim 1 is discussed above.

The Krzysik, et al. reference is discussed above. Significantly, Krzysik, et al. fail to disclose or suggest a composition including from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof. Bowser, et al. fail to overcome this shortcoming.

Specifically, Bowser, et al. is directed to a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain ω -hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the skin in an appropriate dilution. One suitable vehicle is water.

In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

Significantly, as with the Krzysik, et al. reference, Bowser, et al. fail to teach or suggest a composition comprising from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthocyanidins, and mixtures thereof. At best, Krzysik, et al. and Bowser, et al. both generally disclose the inclusion of an antioxidant as an additional ingredient in their compositions, and Bowser, et al. further disclose that their composition may include from 0.005% to 5% by weight of an active ingredient, such as a physiologically acceptable autoxidation inhibitor. Nowhere, however, do either of the cited references disclose or suggest any of the specific antioxidants as are required by Applicants' amended claim 1. As such, claim 1 is submitted to be patentable over the cited references.

Moreover, even if the combination of Krzysik, et al. and Bowser, et al. did teach or suggest each and every element of Applicants' claim 1 (which, as noted above, Applicants respectfully assert that the references do not), the common sense of one of ordinary skill in the art would not have provided a reason to modify and/or combine the cited references to arrive at Applicants' amended claim 1. Specifically, although Krzysik, et al. and Bowser, et al. generally disclose the inclusion of an antioxidant as an additional ingredient, and

Bowser, et al. further disclose suitable autoxidation inhibitors for the inclusion in their composition, nowhere do either Krzysik, et al. or Bowser, et al. disclose the specific antioxidants as are required by Applicants' amended claim 1. As such, what reason would one have to modify and/or combine the cited references to arrive at Applicants' amended claim 1, which requires the inclusion of compounds nowhere even mentioned in either of the cited references? Moreover, as Bowser, et al. already disclose suitable autoxidation inhibitors for their composition, what reason would one skilled in the art have to modify Bowser, et al. to include different antioxidants than those listed, much less the specific antioxidants required by Applicants' amended claim 1? Applicants submit that one skilled in the art would not and could not have a reason to modify the references to arrive at Applicants' claimed invention. As such, claim 1 is submitted to be patentable over the cited references.

Claims 23 and 24 depend from claim 1 and are therefore patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

Independent claim 32 is similar to claim 1 and further requires the moisturizing and lubricating composition to comprise a dispersing agent. As such, claim 32 is patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires.

Claims 56 and 57 depend directly or indirectly from claim 32 and are therefore patentable over the cited references for

the same reasons as set forth above for claim 32 as well as for the additional elements they require.

Claim 62 is similar to claim 1 and further requires the immobilizing agent to be a high molecular weight polyethylene glycol selected from the group consisting of PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. As such, claim 62 is patentable over the cited references for the same reasons as claim 1, as well as for the additional limitations it requires.

Claim 67 which depends from claim 62, is patentable over the cited references for the same reasons as claim 62, as well as for the additional limitations it requires.

3. Rejections under 35 U.S.C. § 103(a) over Krzysik, et al. in view of Vega, et al.

Reconsideration is requested of the rejection of claims 1, 31, 61, and 69 under 35 U.S.C. § 103(a) as being unpatentable over Krzysik, et al. in view of Vega, et al. (U.S. Patent No. 6,153,209).

Claim 1 is discussed above.

The Krzysik, et al. reference is discussed above. Significantly, Krzysik, et al. fail to disclose or suggest a composition including from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthrocyanidins, and mixtures thereof. Vega, et al. fail to overcome this shortcoming.

Specifically, Vega, et al. is directed to absorbent articles having a skin care composition deposited on at least a portion of the article. The skin care composition is a breathable, barrier protectant which can be immobilized on the article and is transferable to the wearer's skin via contact, normal wearer motion, and/or body heat. The skin care composition may comprise an emollient in an amount of from about 5 to about 95 wt.% of the skin care composition; an immobilizing agent in an amount of from about 5 to about 95 wt.% of the skin care composition, and optionally a humectant. The composition may also include an antioxidant, such as ascorbic acid, tocopherol, tocopherol acetate, and mixed tocopherol. Vega, et al. state that the compositions preferably fully melt at a temperature significantly above room temperature, and typically are applied to the article by heating the composition to a temperature in the range from about 35°C to about 150°C prior to application. Vega, et al. also state that the compositions preferably have a melt profile wherein 2-50% of the composition is liquid at room temperature (20°C).

As with the Krzysik, et al. reference, Vega, et al. fail to disclose a composition comprising from about 0.05% (by weight) to about 5% (by weight) of an antioxidant selected from the group consisting of butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), carotenoids, gamma oryzanol, sodium sulfite, green tea extract, rosmarinic acid, ubiquinone, lipoic acid, N-acetyl-cysteine, proanthrocyanidins, and mixtures thereof. Applicants further submit that there is no reason for

one skilled in the art to be motivated to modify and/or combine the cited references to arrive at Applicants' claimed invention.

Specifically, even if the combination of Krzysik, et al. and Vega, et al. did teach or suggest each and every element of Applicants' claim 1 (which, as noted above, Applicants respectfully assert that the references do not), the common sense of one of ordinary skill in the art would not have provided a reason to modify and/or combine the cited references to arrive at Applicants' amended claim 1. Specifically, although Krzysik, et al. generally disclose the inclusion of an antioxidant as an additional ingredient, and Vega, et al. disclose suitable antioxidants for the inclusion in their composition when needed, nowhere do either Krzysik, et al. or Vega, et al. disclose the specific antioxidants as are required by Applicants' amended claim 1. As such, what reason would one have to modify and/or combine the cited references to arrive at Applicants' amended claim 1, which requires the inclusion of compounds nowhere even mentioned in either of the cited references? Moreover, as Vega, et al. already disclose suitable antioxidants for their composition, what reason would one skilled in the art have to modify Vega, et al. to include different antioxidants than those listed, much less the specific antioxidants required by Applicants' amended claim 1? Applicants submit that one skilled in the art would not and could not have a reason to modify and/or combine the references to arrive at Applicants' claimed invention. With all due respect, it appears that the Office has engaged in hindsight reasoning in combining the cited references, which the Federal

Circuit has consistently warned against. As such, claim 1 is submitted to be patentable over the cited references.

Claim 31 depends from claim 1 and is therefore patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements it requires.

Independent claim 32 is similar to claim 1 and further requires the moisturizing and lubricating composition to comprise a dispersing agent. As such, claim 32 is patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional limitations it requires.

Claim 61 depends from claim 32 and is therefore patentable over the cited references for the same reasons as set forth above for claim 32 as well as for the additional elements it requires.

Claim 62 is similar to claim 1 and further requires the immobilizing agent to be a high molecular weight polyethylene glycol selected from the group consisting of PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. As such, claim 62 is patentable over the cited references for the same reasons as claim 1, as well as for the additional limitations it requires.

Claim 69 which depends from claim 62, is patentable over the cited references for the same reasons as claim 62, as well as for the additional limitations it requires.

4. Double Patenting Rejections

Claims 1-8, 10, 12-33, 35-40, 42, and 44-74 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,862 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.

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CONCLUSION

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-8, 10, 12-33, 35-40, 42, and 44-74 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required during the entire pendency of this application to Deposit Account No. 01-2384.

Respectfully Submitted,

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